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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GRAY, PHILLIP A	

ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/752,257	GIRARD ET AL.	
	Examiner	Art Unit	
	PHILLIP GRAY	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/28/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to applicant's communication of 5/16/2011. Currently amended claims 1, 3-18 are pending and stand rejected below.

Response to Arguments

Applicant's arguments filed 5/16/2011 have been fully considered but they are not persuasive. Applicant's argue that Miller septum is not "formed as a one piece whole" or is unitary. Examiner disagrees.

Examiner is maintaining the previous office actions rejections. Again, It is examiners position that "unitary" means:

. u·ni·tar·y

-adjective

1.
of or pertaining to a unit or units.
2.
of, pertaining to, characterized by, or aiming toward unity: *the unitary principles of nationalism.*
3.
of the nature of a unit; having the indivisible character of a unit; whole.
4.
serving as a unit, as of measurement or estimation.
5.
of or pertaining to the use of units: *A unitary method was applied.*
6.
Government . of or pertaining to a system of government in which the executive, legislative, and judicial powers of each state in a body of states are vested in a central authority

Given the broadest reasonable definition of the term "unitary" and formed as a one piece whole, it is examiners postion that the Miller septum (specifically see figures

5-7 which show the onepiece unitary configuration and formation) therefore without evidence to the contrary it is examiners position that this would be considered a unitary body. Again, the fact that it may be "divisible" does not negate position that the Miller septum is pertating to the unit of the septum, is formed as a one piece whole, and has the indivisible character of the unit or whole of the septum. Evidence of this is shown in Miller figures 6-7 element 52 and the whole one piece of 32. Again, therefore examiner is reading this structure of the septum as being a "unitary body" and maintaining the rejection. Further examiner is of the position that the term valve stem is within the broadest reasonable definition of the term, particularly the element disclosed in Miller (the valve stem) closes off the valve when not in use is similar in function to the applicants septum which closes off the orifice when not in use.

Concerning the position that the Miller art fails to disclose a chamfered portion which redirects the perpendicular force to compress the operative surface in a ddirection parallel to the annular surface, examiner disagrees.

It is examiners position that It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitation of the claim. Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In addition, where

there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon.

In the instant case it is examiners position that Miller discloses a chamfer (44), figure 5-7 shows that the annular surface extends radially beyond a periphery of the operative surface and separated in a direction perpendicular to that annular surface and coupled by the annular surface, (see figure 3-4), and further that when septum is mounted in housing there is a force oriented substantially perpendicular to the annular plane (force near 44) and the chamfered portion redirects the force to compress the operative surface in a substantially parallel to the annular surface (note change in shape and orientation from septum in figure 5 and when mounted in figure 3).

Under this rational the elements disclosed in Miller and any obvious modifications thereof, are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made and proper. See rejection discussion below.

It is recommended applicant amend the claims to greater specify the structures if that is where they fell novelty lies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (U.S. Patent Pub US2003/0141477 A1). Again Miller discloses an access port (see figures 3-6) comprising a housing (26) with first and second openings (near 20 and 24), a septum forming a unitary body (52 or 32) mounted within housing (see figures 3-6) with an operable surface (46), attachment surface (near 62 that is near 40 towards base of housing (56) , and chamfer (44) that is . It is examiners position that figure 5-7 shows that the annular surface extends radially beyond a periphery of the operative surface

and separated in a direction perpendicular to that annular surface and coupled by the annular surface, (see figure 3-4), and further that when septum is mounted in housing there is a force oriented substantially perpendicular to the annular plane (force near 44) and the chamfered portion redirects the force to compress the operative surface in a substantially parallel to the annular surface (note change in shape and orientation from septum in figure 5 and when mounted in figure 3).

Concerning the first and second openings "adapted to connect to a catheter and is substantially perpendicular to the first opening", in cases like the present, where patentability is said to be based upon particular chosen dimensions or upon another variable recited within the claims, applicant must show that the chosen dimensions are critical. As such, the claimed dimensions appear to be an obvious matter of engineering design choice and thus, while being a difference, does not serve in any way to patentably distinguish the claimed invention from the applied prior art. Miller discloses the claimed invention except for the first and second openings being perpendicular to one another. It would have been an obvious matter of design choice to form the first and second openings perpendicular to one another, since applicant has not disclosed that the openings being perpendicular to one another solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the first and second openings collinear, perpendicular, or and any other angle to one another. Surgical tubing and ports are well known to form many angled, linear, or perpendicular configurations in order to effectively route the fluid in the given direction to and from a patient. In the present case forming the openings in a

linear, perpendicular or angled relationship would allow the transfer of fluid to take place in a desired most efficient distance path.

Concerning claim 3 note seat on interior of housing near 56 and cover 28. Concerning claim 4-5 note angled surface in figure 5 near 44. Concerning claim 6 and 16-17 note stepped chamfer (chamfer 44 near 38 as discussed above and stepped portion 39). Concerning claim 7-8, 15 see figure 6 of chamfer on the peripheral edge of 44 or 58 and note curved constant radius. Concerning claim 9 note septum 32 abuts septum seat (interior of housing near 64) of housing. Concerning claim 10 see figure 3. Concerning claim 11, 13, 14 compare figure 5 with figure 3. Concerning claim 12 see rejection of claim 1 above. Concerning claim 18 see paragraphs [0032].

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller (U.S. Patent Pub US2003/0141477 A1). Again, Miller discloses an access port (see figures 3-6) comprising a housing (26) with opening (near 23), a septum forming a unitary body (52 or 32) mounted within housing (see figures 3-6) with an operable surface (46), attachment surface (near 62 that is near 40 towards base of housing (56) ,

and chamfer (44) that is . It is examiners position that figure 5-7 shows that the annular surface extends radially beyond a periphery of the operative surface and separated in a direction perpendicular to that annular surface and coupled by the annular surface, (see figure 3-4), and further that when septum is mounted in housing there is a force oriented substantially perpendicular to the annular plane (force near 44) and the chamfered portion redirects the force to compress the operative surface in a substantially parallel to the annular surface (note change in shape and orientation from septum in figure 5 and when mounted in figure 3).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILLIP GRAY whose telephone number is (571)272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phillip Gray/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/
Supervisory Patent Examiner, Art Unit 3767